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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Physiologic Predictors of the Need for Trauma Center Care: A Systematic Review.

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of *Physiologic Predictors of the Need for Trauma Center Care: A Systematic Review*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES:

E-mail submissions: SEADS@epc-src.org.

Print submissions:

Mailing Address:

Portland VA Research Foundation

Scientific Resource Center
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FOR FURTHER INFORMATION CONTACT:

Ryan McKenna, Telephone: 503-220-8262 ext. 51723 or Email: SEADS@epc-src.org.

SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality (AHRQ) has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Physiologic Predictors of the Need for Trauma Center Care: A Systematic Review*. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Physiologic Predictors of the Need for Trauma Center Care: A Systematic Review*, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at:

<https://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=2435>

This is to notify the public that the EPC Program would find the following information on *Physiologic Predictors of the Need for Trauma Center Care: A Systematic Review* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
 - *For completed studies that do not have results on ClinicalTrials.gov, please provide a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.*
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. The contents of all submissions will be made available to the public upon request so materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is

a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at:

<https://www.effectivehealthcare.ahrq.gov/index.cfm/join-the-email-list1/>.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

The Key Questions

Key Question 1

For patients with known or suspected trauma who are treated out-of-hospital by Emergency Medical System (EMS) personnel, what is the predictive utility of measures of circulatory compromise (e.g., systolic blood pressure, mean arterial pressure, heart rate, heart rate complexity/variability) or derivative measures (e.g., the shock index) for predicting serious injury requiring transport to the highest level trauma center available?

- I. How does the predictive utility of the studied measures of circulatory compromise vary across age groups (e.g., children or the elderly)? Specifically, what age ranges and values for the different age ranges are supported by the evidence?

Key Question 2

For patients with known or suspected trauma who are treated out-of-hospital by EMS personnel, what is the predictive utility of measures of respiratory compromise, (e.g., ventilatory support, respiration rate, tissue O₂ saturation, respiratory effort, measures of

acidemia such as end-tidal CO₂, lactate, or base deficit) for predicting serious injury requiring transport to the highest level trauma center available?

- I. How does the predictive utility of the studied measures of respiratory compromise vary across age groups (e.g., children or the elderly)? Specifically, what age ranges and values for the different age ranges are supported by the evidence?

Key Question 3

For patients with known or suspected trauma who are treated out of the hospital by EMS personnel, what is the predictive utility for combinations of measures of respiratory and circulatory compromise together with or without measures of altered levels of consciousness (as defined by Glasgow coma scale or its components), for predicting serious injury requiring transport to the highest level trauma center available?

- I. How does the predictive utility of combinations of measures vary across age groups (e.g., children or the elderly)? Specifically, what age ranges and values for the different age ranges are supported by the evidence?

Using the PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings) framework and a graphical analytic framework required adapting these tools as they were designed for and usually used for intervention studies. Our approach is informed by guidance related to frameworks in the Methods Guide for Systematic Reviews of Diagnostic Tests in addition to the Methods Guide for Effectiveness and Comparative Effectiveness Reviews. We have included the standard PICOTS terms, but added detail to explain how we are using them for this review and we have added a legend and text to the graphical framework.

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

Population(s)

Population refers to the patients who are the subjects in the studies to be included.

Include: Studies of patients of any age with known or suspected trauma who require assessment of physiologic compromise by EMS out of the hospital

Exclude: Studies of patients with nontrauma conditions or illnesses, patients with burns or chemical exposures, healthy people, and animal studies, Studies of patients in which other assessments are used (e.g., type of injury) or in which the patient population is limited to a subgroup of patients defined as seriously injured.

- Studies in which the patient population is a priori restricted to patients with serious traumatic injuries
- Studies in which all patients have injuries that can be assessed or would be defined as serious based on direct observation (e.g., an amputation)

Interventions (Physiologic Measures)

The intervention is usually the treatment or health service of interest that is being evaluated in terms of its impact on the population. In this review the physiologic measures are what are evaluated. This review will include any measure of circulatory or respiratory compromise or combination measures. Examples are provided for each Key Question; however, additional measures may be identified by the search.

Include:

- I. Key Question 1: Physiologic measures of circulatory compromise, including but not limited to systolic blood pressure, mean arterial pressure, heart rate, heart rate complexity/variability, or derivative measures such as the shock index

- II. Key Question 2: Physiologic measures of respiratory compromise or effort, including but not limited to respiration rate, tissue O2 saturation, respiratory effort, measure of acidemia (e.g., end-tidal CO2, lactate, base deficit), or advanced out-of-hospital airway intervention
- III. Key Question 3: Combinations of measures of respiratory and circulatory compromise with or without measures of altered levels of consciousness (as defined by Glasgow coma scale or its components)
- IV. All Key Questions: Additional measures may be identified during the search and included based on input from clinical experts. Studies of newer devices that provide these or other measurements will be included if available and relevant.

In all cases measurement can be for a single point in time, change over time, or can be trends in the measure evaluated by a person or technology.

Exclude: Clinical assessment or indicator of health status that is not a separate indicator or a combination indicator including a measure of circulatory or respiratory compromise (e.g., temperature, consciousness, eye tracking, musculoskeletal soundness, balance, blood glucose, orientation).

Comparisons and Outcomes

As this is not a review of intervention studies, the structure of the questions for the review as well as the questions posed by included studies are different. The Key Questions address how well measures of physiologic compromise identify trauma patients likely to have a serious injury requiring high-level trauma care.

We include two types of evaluations of measures: (1) studies of how well single measures predict severe injury; and (2) studies that compare the performance of two or more measures directly (head-to-head studies).

The end points or "outcomes" of interest are the predictive utility of the measures. We include three different approaches to assessing predictive utility: (1) adjusted risk

estimates (e.g., odds ratio, relative risk, hazards ratio); (2) discrimination (e.g., area under the receiver operating characteristic curve [AUROC]); and (3) measures of diagnostic accuracy (e.g., sensitivity, specificity, positive predictive values, and negative predictive values).

The predictive utility is defined in terms of the physiologic measure's ability to identify patients who have severe injury. Defining and operationalizing what "severe injury" means is challenging for several reasons. Whether a patient had a serious injury at the time of field triage cannot be determined conclusively and we expect that clinical outcomes (e.g., death or disability) are affected by out-of-hospital and in-hospital treatment (i.e., a person can have a serious injury and recover). For this reason, we accept several indicators that a patient was seriously injured. These include outcomes, such as death, whether the patient required treatments and interventions used for serious injury, or whether the injury is rated as severe using accepted rating scales. It is possible the review will identify additional indicators that a patient had a severe injury; however the following list includes those that have been used in prior research.

Indicators of serious injury

- I. In-hospital mortality
- II. Resource use/intervention standards or lists
 - a. Published Consensus-Based Criterion Standard — This list defines need for trauma center care as any one of the following 10 specific indicators: major surgery, advanced airway, blood products, admission for spinal cord injury, thoracotomy, pericardiocentesis, cesarean delivery, intracranial pressure monitoring, interventional radiology, and in-hospital death.
 - b. Need For Life-Saving Interventions — Lists used by the U.S. military that include angioembolization, blood transfusion, cardiopulmonary resuscitation, chest tube, intubation, needle decompression, surgical cricothyrotomy or thoracotomy, pericardiocentesis, angiography with embolization, angiography without and surgical intervention.

- c. Major Surgery — Not including orthopedic surgery
- d. Ratings of Injury Severity — Injury Severity Score (ISS) >15, as this is a commonly used threshold for high risk patients, but other cut-offs will be considered if used in included studies. The ISS score is based on an assessment that divides the body into nine regions, classifies the level of injury in each of the three most severely injured regions on a scale of 1 to 6, squares these values, and adds them together.

Timing

Physiological measures upon the arrival of EMS personnel to the scene of injury, during treatment in the field, and during transport (referred to as out-of-hospital or in the field). Studies with measures taken upon arrival at an emergency department will be considered. Details about timing of measurement will be recorded in data abstraction if they are reported.

Settings

Include:

- I. Studies measuring physiologic compromise in the field/out of hospital
- II. Studies of initial ED measurement as indirect evidence only if out of hospital evidence is not available and the measure is deemed clinically relevant
- III. Studies conducted in civilian or military settings

Exclude:

- I. Inpatient, clinic, or emergency department (ED)
- II. Studies conducted in developing countries with out-of-hospital care systems that differ from those in the United States

Study Designs

Include:

- I. Any study that assesses the predictive utility of included measures either individually or that compares two or more measures. Designs may include trials and prospective and retrospective observational studies
 - a. Systematic reviews

Exclude:

- I. Nonsystematic reviews, commentaries, and letters
- II. Descriptions of the properties or performance of measures that do not include predictive utility

Sharon B. Arnold
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